UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PharmacyChecker.com LLC, *Plaintiff*, vs. National Association of Boards of Pharmacy et al., *Defendants*.	Civil Action No. 7:19-cv-07577-KMK **Plaintiff's Opposition to Defendants' Joint Motion for Summary Judgment on Sherman Act § 1 Claim** ORAL ARGUMENT REQUESTED Judge Kenneth M. Karas Magistrate Judge Paul E. Davison

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Defendants ask the Court to strip plaintiff of its antitrust rights because they claim plaintiff's business is almost completely geared toward facilitating illegality. This is not the applicable legal standard, and defendants' massive evidentiary submission demonstrates it would be impossibly convoluted to apply.

Even so, defendants do not meet that standard under their version of the undisputed facts. Just ahead of defendants' motion, their expert amended his report because of "recently discovered errors" in the data he relied on. Defendants staked their pre-motion argument on the expert's claim that more than [redacted] of plaintiff's click-through revenue came from U.S. visitors clicking to non-U.S. websites; the revised number is now [redacted].

Taking that figure as true, only [redacted] of plaintiff's total revenue even potentially implicates U.S. importation law. That is not "almost completely." But if it were, defendants offer no evidence to support their assumptions connecting clicks to unlawful U.S. importations, and factual disputes abound. Regardless, defendants cannot remove plaintiff's antitrust rights for having too many foreign pharmacies relative to U.S. pharmacies when the reason more U.S. pharmacies don't participate is the very anticompetitive conduct that caused plaintiff's antitrust injury.

BACKGROUND

This antitrust case is about a decade-plus-long scheme among direct competitors and a network of organizations funded by pharmaceutical manufacturers, large pharmacy chains, and other pharmacy interests to use shadow regulation by agreements with key internet gatekeepers to manipulate and suppress the information available to consumers about lower-cost, safe prescription medicine

on the Internet. As a result of this scheme, plaintiff was effectively excluded from the market, which harmed competition and injured plaintiff.

Relevant Procedural History

Plaintiff filed its complaint August 13, 2019, alleging one claim under Sherman Act Section 1 against all defendants and one claim for false advertising under the Lanham Act against defendant NABP. Dkt. 1. The court denied a preliminary injunction, and plaintiff amended its complaint October 21, 2019. Dkt. 82.

On March 13, 2020, defendants filed a joint motion to dismiss arguing, among other grounds, that plaintiff's antitrust claim should be dismissed because "its asserted harm arises out of Defendants' alleged acts suppressing unlawful drug importation." Dkt. 101 at 16. The Court denied the motion, concluding the amended complaint "does not establish that Plaintiff's enterprise is completely or almost completely illegal or geared towards illegality." Dkt. 129 at 27. It added that "If discovery supports Defendants' claim that the 'primary purpose of Plaintiff's business is to facilitate unlawful importation,' . . . it may advance the same argument at that juncture." *Id*. at 27–28 (quoting Dkt. 101 at 1).

Defendants proposed "a brief, five-month initial discovery phase . . . focused solely on . . . whether [plaintiff's] business is 'completely or almost completely geared towards facilitating illegality.' " Dkt. 163-2 at 1 (quoting Dkt. 129 at 26). Defendants proposed "surgical" discovery on an "abbreviated timeframe." *Id.* The Court granted defendants' proposal, limiting Phase 1 to discovery from plaintiff and third parties only on the "legality of Plaintiff's business model." Dkt. 166 at 3.

Unfortunately, this "surgical" discovery became a full-scale examination of every aspect of plaintiff's small business. Defendants issued 38 broad document requests such as "All Documents and Communications Concerning any and all audits of Plaintiff, including all Documents and Communications provided to or from any Person involved in performing such audit" PX 42, RFP No. 5; and "All Documents concerning any actual or potential investors or investments in Your business, including all Communications with actual and potential investors" *Id.* at RFP No. 6, plus 11 interrogatories. Defendants took broad license to demand more than 400,000 pages of documents and that plaintiff generate new reports not run in the ordinary course of business, resulting in a four-month extension of their "brief" five-month schedule.

Statement of Facts

PharmacyChecker.com launched in 2003 to promote consumer health by evaluating the practices of online pharmacies. Plaintiff's Local Rule 56.1 Statement of Material Facts in Opp'n to Defs.' Mot. for Summ. J. ("PSOF") ¶ 1.[1] It operates a rigorous accreditation program to inform visitors about online pharmacies and provides drug price comparison information for visitors worldwide, helping people find the lowest prices and raising awareness about policy problems around prescription drug access and affordability. ¶ 12. Plaintiff is not a pharmacy and is not engaged in the order, sale, dispensing, or distribution of any drugs. ¶ 96.

Plaintiff's online pharmacy verifications and drug price comparisons are

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1. All paragraph references are to PSOF unless otherwise noted.

widely trusted and referenced in media sources including AARP Magazine, the Wall Street Journal, Yahoo Finance, the New York Times, Kaiser Health News, and many others. ¶ 95. It is one of few resources giving transparency to prescription drug prices, allowing them insight into a drug industry that charges U.S. patients far more than in other countries. ¶ 12. Its drug price comparisons have been cited by the FDA and academic researchers. *Id*. Organizations such as Medicines Sans Frontiers (i.e., Doctors Without Borders) have sought advice from plaintiff on international pharmacy safety and drug pricing. *Id*.

Plaintiff provides its information services to visitors of its website for free, like many of the most prominent websites that exist today. Rather than charge visitors for this information, plaintiff supports its website and programs with revenue from several different categories. ¶15. About [redacted] of plaintiff's revenue from January 2015 to August 2021 came from click-through revenues paid by online pharmacies for each click to their website from PharmacyChecker.com from a visitor, regardless of the visitor's geographic location. ¶ 8. Another [redacted] of plaintiff's revenue comes from verification program fees, including fees for initial accreditation and fees for ongoing monitoring paid by participating online pharmacies. *Id*. Only verified pharmacies may participate in the drug listing comparison program. ¶ 16. Remaining revenue came from other sources such as its prescription drug discount card, Medicare drug plans, advertising, and e-books. ¶ 10.

PharmacyChecker.com's web traffic comprises visitors from 220 countries from 2015 to 2021. ¶ 56. About [redacted] of its traffic was from the United States versus

[redacted] foreign. *Id.* About [redacted] of unique visitors to the site never click through to a pharmacy's website, and thus does not affect plaintiff's click-through revenue. *Id.* Some website visitors use the information on the website as a reference for comparative shopping, for research, for policy advocacy, or as an educational tool. ¶ 44. Some visitors use plaintiff's U.S. prescription drug discount card to fill prescriptions in the United States. ¶ 11.

Of visitors who click through to an online pharmacy website, [redacted] are in the United States, while [redacted] are outside the United States. ¶ 40. Pharmacies based outside the United States contributed [redacted] of plaintiff's accreditation fee revenue, with U.S. online pharmacies contributing between [redacted] and [redacted] of the remaining revenue. ¶¶ 22, 32. About [redacted] of plaintiff's total click-through revenue was from clicks to online pharmacies located outside the United States (but only [redacted] of that revenue came from clicks by visitors in the United States). *Id.* Only [redacted] of plaintiff's total revenue came from clicks by U.S. users to non-U.S. online pharmacies. ¶ 32. Fewer U.S. pharmacies have participated in plaintiff's programs in recent years because of defendants' efforts to coerce or dissuade them from participating in plaintiff's verification and listing programs. ¶¶ 24–25, 28 ([redacted] U.S. pharmacies from 2015–2021).

As one example, [redacted], one of the largest U.S. online pharmacies, left plaintiff's verification program in 2017 when defendant NABP threatened its VIPPS accreditation. ¶ 24. VIPPS accreditation is key for U.S. online pharmacies because it is required for a .pharmacy domain name (the pharmacy top-

level-domain was proposed by defendants and managed by NABP). *Id.* In 2018, NABP again threatened to strip [redacted]'s VIPPS accreditation if it publicly associated with plaintiff. *Id.* Defendants have also run U.S.-targeted advertisements using "pharmacychecker" as an AdWord to dissuade both online pharmacies and consumers from associating with or using plaintiff's services. *Id.* Plaintiff does not know how many other U.S. online pharmacies have been coerced or dissuaded by defendants.

Plaintiff does not track visitor activity after clicking through to a pharmacy website, and it has no data connecting clicks to transactions. ¶ 22. It does not receive such information from pharmacies that participate in its programs. ¶ 32. Plaintiff earns revenue when visitors click through to pharmacies, but none of that revenue depends on transactions (except for the U.S. prescription drug discount card). ¶¶32, 40. According to one pharmacy's testimony, [redacted] of its clicks led to a transaction. ¶ 22.

LEGAL STANDARD

Summary judgment should be granted only where the movant shows "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Psihoyos v. John Wiley & Sons, Inc.*, 748 F.3d 120, 123–24 (2d Cir. 2014). A court must "construe the facts in the light most favorable to the non-moving party and . . . resolve all ambiguities and draw all reasonable inferences against the movant." *Brod v. Omya, Inc.*, 653 F.3d 156, 164 (2d Cir. 2011); *see also Borough of Upper Saddle River v. Rockland Cnty. Sewer Dist. No. 1*, 16 F. Supp. 3d 294, 314 (S.D.N.Y. 2014) (same). "It is the movant's

burden to show that no genuine factual dispute exists." *Vt. Teddy Bear Co. v. 1-800 Beargram Co.*, 373 F.3d 241, 244 (2d Cir. 2004); *see also Shamrock Power Sales, LLC v. Scherer*, No. 12-CV-8959 (KMK), 2015 U.S. Dist. LEXIS 133650, at *68 (S.D.N.Y. Sept. 30, 2015).

A fact is "material if it 'might affect the outcome of the suit under the governing law.' " *Royal Crown Day Care LLC v. Dep't of Health & Mental Hygiene*, 746 F.3d 538, 544 (2d Cir. 2014). "The role of the court is not to resolve disputed issues of fact but to assess whether there are any factual issues to be tried." *Brod*, 653 F.3d at 164; *see also In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, MDL No. 1358, No. M21-88, 2014 WL 840955, at *2 (S.D.N.Y. Mar. 3, 2014) (same).

ARGUMENT

The Court should not add the new antitrust injury requirement sought by defendants. Instead, it should apply controlling law: a plaintiff cannot show antitrust injury where the law—rather than defendants—restrained competition and caused plaintiff's injury. Defendants concede plaintiff's business is not itself illegal. Even if the Court does apply defendants' flawed approach of slicing and dicing plaintiff's business, defendants' own count comes up short: only [redacted] of plaintiff's business could even potentially implicate U.S. importation law. Plaintiff's business cannot be "almost completely geared toward facilitating illegality." Mem. of Law in Supp. of Defs.' Joint Mot. for Summ. J. on Sherman Act § 1 Claim at 4 (Mem.) (Dkt. 264). Defendants do not meet their initial burden, but there are also genuine disputes of fact that preclude summary judgment. Finally, defendants' group boycott thwarted plaintiff's efforts to list U.S. online pharmacies, and they cannot use the

results of their own anticompetitive conduct as a shield from antitrust liability.

I. THE COURT SHOULD NOT ADD NEW ANTITRUST INJURY REQUIREMENTS CONTRARY TO CONTROLLING LAW

A. Antitrust Standing Is Not Removed by Plaintiff's Conduct

At the pleadings stage, the Court did not "consider Plaintiff's argument that it has antitrust standing because the Sherman Act is important, and because equitable defenses like unclean hands and the doctrine of *in pari delicto* do not defeat a Sherman Act claim." MTD Order at 27 n.12 (Dkt. 129) (noting that the court in *Realnetworks, Inc. v. DVD Copy Control Ass'n, Inc.*, No. 08-CV-4548, 2010 WL 145098, at *6 (N.D. Cal. Jan. 6, 2010), distinguished equitable defenses from establishing antitrust injury). Plaintiff reasserts the argument here that a federal court may not decline to enforce Section 1 of the Sherman Act on the purported basis that a plaintiff's business is "completely or almost completely geared toward facilitating" unlawful conduct by others. Mem. at 4.

The Supreme Court rejected an "unclean hands" exemption from the federal antitrust laws, even when the plaintiff's own conduct is a felony antitrust violation. *Kiefer-Stewart Co. v. Joseph E. Seagram & Sons, Inc.*, 340 U.S. 211, 214 (1951), *overruled on other grounds by Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752 (1984) ("The alleged illegal conduct of petitioner, however, could not legalize the unlawful combination by respondents nor immunize them against liability to those they injured."); *Perma Life Mufflers v. Int'l Parts Corp.*, 392 U.S. 134, 139 (1968) (If a plaintiff did something unlawful, she remains "fully subject to civil and criminal penalties for [her] own illegal conduct."); I Phillip E. Areeda & Herbert

Hovenkamp, *Antitrust Law* ¶361. (4th ed. 2018); *see also Memorex Corp. v. IBM Corp.*, 555 F.2d 1379, 1382 (9th Cir. 1977) ("A wrongful act committed against one who violates the antitrust laws must not become a shield in the violator's hands against the operation of the antitrust laws.").

Although in these cases the Court most directly abolished equitable defenses, their reasoning demands rejecting defendants' wish to remove antitrust standing based on self-serving rhetoric that plaintiff's conduct is wrongful. The Second Circuit did just that when it held that a cartel member has antitrust standing to sue its co-conspirators, despite its own illegal conduct, so long as the plaintiff's "interest coincides with the public interest in vigorous competition." *Volvo N. Am. Corp. v. Men's Int'l Pro. Tennis Council*, 857 F.2d 55, 67–68 (2d Cir. 1988) (citing *Perma Life*, 392 U.S. at 139–40); *see also Kolon Indus., Inc. v. E.I. du Pont de Nemours & Co.*, No. 3:11cv622, 2012 WL 1155218, at *9 (E.D. Va. Apr. 5, 2012) (Plaintiff's "wrongful conduct does not render [defendant] immune from antitrust suit.") (citing *Perma Life*, 392 U.S. at 139).

In *Calnetics Corp. v. Volkswagen of America, Inc.*, the Ninth Circuit similarly declined to exclude damages incurred when plaintiff's business was illegal because the argument is "in effect" an "unclean hands" defense, "which is not a defense in an action for treble damages." 532 F.2d 674, 688 (9th Cir. 1976). It reasoned that "[l]abels . . . are not controlling, and we find no legitimate reason for distinguishing defendants' 'illegal sales' argument from the *in pari delicto* type of defense struck

down in *Perma Life*."[2] *Id.* at 689. And in *Memorex*, 555 F.2d at 1381, where the plaintiff allegedly stole trade secrets, the court rejected an "unlawful market presence" defense as indistinguishable from the equitable defense rejected in *Perma Life*: "illegality on the part of the plaintiff is the common nucleus of all of these defenses," all rejected under the same rationale: vigorous antitrust enforcement.

Removing standing also conflicts with the Supreme Court's admonishment that courts "not add requirements to burden the private [antitrust] litigant beyond what is specifically set forth by Congress in those laws," and its forceful rejection of various pleas for exceptions—even for dangerous goods and services—because to do so "would be tantamount to repeal of" the Sherman Act. *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 547 n.1 (1983) (quoting *Radovich v. NFL*, 352 U.S. 445, 453–54 (1957)); *Nat'l Soc'y of Pro. Eng'rs v. United States*, 435 U.S. 679, 695 (1978).

Finally, this is the wrong case to adopt a rule that unclean hands removes standing. Defendants do not claim that plaintiff's business itself is illegal. Indeed, that fact is undisputed. ¶ 57; *see* Mem. at 9. Congress never invited private litigants to enforce drug importation laws, but Congress ***did*** empower victims of antitrust conspiracies to enforce the Sherman Act. This Court should decline the invitation to

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2. The Supreme Court has repeatedly held that labels do not drive antitrust policy and that function rather than form controls antitrust case outcomes. *Am. Needle, Inc. v. NFL*, 560 U.S. 183, 195 (2010) ("substance, not form" determines defendants' liability for conspiring to restrain trade); *N.C. State Bd. of Dental Exam'rs v. FTC*, 574 U.S. 494, 511 (2015) (Immunity from liability "does not derive from nomenclature alone.").

repudiate longstanding congressional policy and high-court precedent. *United States v. Topco Assocs.*, 405 U.S. 596, 610 (1972) (federal antitrust laws are the "Magna Carta of free enterprise," as important to interstate commerce and economic liberty "as the Bill of Rights is to the protection of our fundamental personal freedoms"); *Minn. Mining & Mfg. Co. v. N.J. Wood Finishing Co.*, 381 U.S. 311, 318–19 (1965) (Congress relies on antitrust victims to act as private attorneys general through trebled damages and attorneys' fees under the Clayton Act.).

B. Controlling Authorities Rightly Focus on Whether Law or Defendants Caused Plaintiff's Injuries

If there is a correct standard for removing antitrust standing, "almost completely geared toward facilitating," illegality is not it. Mem. at 4. Since the motion-to-dismiss order, this marks plaintiff's first opportunity to litigate the appropriate standard for determining standing. On the motion to dismiss, the Court said:

> While legality is not formally an element of this [standing] inquiry, it is clear to the Court that if an enterprise is completely or almost completely geared toward facilitating illegality, then the type of injury caused by allegedly anticompetitive conduct aimed at the enterprise is not an injury that Congress sought to address and prevent via the antitrust laws.

Order at 5, Dkt. 220; *see also* Order at 2, Dkt. 167. Later in its order, the Court articulated this differently—if discovery shows that plaintiff's "primary purpose" is to facilitate unlawful importation, then defendants may advance a standing argument on the merits. Order at 27, Dkt. 129; *see also* Mem. at 4 n.1, 24 (defendants articulating the concept in various ways, e.g., "material share of . . . business," "primarily geared toward," etc.). Respectfully, plaintiff does not take the Court's

comments to be a pre-determination of the operative legal standard, without briefing, for deciding standing in the Second Circuit—rather than setting out the general framework by which discovery could proceed. *See* Order at 24–26, Dkt. 129 (citing only non-binding decisions).

The "almost completely geared toward facilitating" principle is unprecedented (Dkt. 220 at 2); plaintiff knows of no decision applying this standard to remove antitrust standing anywhere. Instead, the most relevant test on these facts—and far more bright-lined than "almost completely geared toward facilitating"—is from the Second Circuit's decision in *National Association of Pharmaceutical Manufacturers, Inc. v. Ayerst Laboratories*, 850 F.2d 904, 913 (2d Cir. 1988). In *Ayerst,* the plaintiff alleged defendant unlawfully discouraged pharmacists from dispensing a generic drug for a particular post-MI treatment. The defendant argued the plaintiff lacked standing because federal law prohibited promoting and labelling its generic drug for post-MI use. The court rejected the argument: "so long as neither federal nor state law prohibited the substitution of generic propranolol for post-MI indications, we believe that [plaintiff] had a protectible interest in deriving revenue from the sale of propranolol for this use" and, therefore, retained its antitrust rights.[3] *Id.*

3. The Second Circuit distinguished cases in which the plaintiffs lost standing where "the alleged antitrust violations would have prevented the plaintiffs from receiving income to which they had no legal right," for example, where plaintiff lacked standing to pursue a claim of monopolization in the market for electrical power "only because the [plaintiff] had no right to provide electrical service until it had received permission from the state public service commission." *Id.* at 913 (citing *Cottonwood Mall Shopping Center, Inc. v. Utah Power & Light Co.*, 440 F.2d 36, 38 (10th Cir. 1971).

In cases like *Realnetworks,* the plaintiffs were also competitors or potential competitors of the defendant like the plaintiff in *Ayerst*. Those cases held, as *Ayerst* did, that the plaintiffs lacked standing because a legal barrier caused their injury—and not the defendants' alleged conduct. In *Realnetworks,* the court said the plaintiff was ***not*** barred from its antitrust claim "because it has engaged in illegal activity; rather the court holds that Real has failed to allege a plausible antitrust injury," as its exclusion was the result of a court injunction rather than defendant's anticompetitive conduct. 2010 WL 145098, at 6 (additionally, the plaintiff's own conduct was undoubtedly "illegal" by itself). Similarly, in *Modesto Irrigation District v. Pacific Gas & Electric Co.*, the plaintiff sued PG&E for failing to provide service but providing service would have been illegal. 309 F. Supp. 2d 1156 (N.D. Cal. 2004), *aff'd*, 158 F. App'x 807 (9th Cir. 2005). Even though the plaintiff's own conduct was also unlawful, the case only stands for the proposition that a legal barrier (no permit) was the actual cause of the plaintiff's injury. *Id*. at 1170. The common thread: the plaintiffs in these cases would have suffered the same injury even had the defendant not engaged in the conduct at issue.

Likewise, in *Monarch Marking Systems, Inc. v. Duncan Parking Meter Maintenance Co.*, the plaintiff retained antitrust standing for periods of time it was legally able to compete because its products were non-infringing; it lost it for periods in which it was legally unable to compete because its products were infringing. No. 82-cv-2599, 1988 WL 23830, at *2–3 (N.D. Ill. Mar. 8, 1988). In *Bubis v. Blanton*, the Sixth Circuit employed the same principle: "a potential competitor has a business

interest protected by the antitrust laws [where it has] both the ***intention*** and ***preparedness*** to compete." 885 F.2d 317, 319 (6th Cir. 1989). That plaintiff lacked preparedness because it had no license to operate. *Id.*

Defendants rely heavily on *In re Canadian Import Antitrust Litigation*, 470 F.3d 785 (8th Cir. 2006), to argue a plaintiff does not suffer antitrust injury where it facilitates "unlawful conduct." Mem. at 27. But the case does not stand for that broad proposition. There, the plaintiff was not a competitor but a class of nationwide prescription drug consumers who alleged they paid higher prices for U.S. drugs because pharmaceutical manufacturers conspired to suppress international pharmacy competition, thus raising the prices of drugs they purchased in the United States. *Canadian Import*, 470 F.3d at 791. The court held the class had not suffered antitrust injury because their injury—higher prices from the lack of international pharmacy competition—was ***not*** caused by the conspiracy suppressing that competition; instead, a regulatory barrier did that. *Id.* The class would have suffered the same injury if defendants had not conspired because their U.S. drug prices would have been the same either way.

Like *Ayerst*, the case reflects the uncontroversial rule that a plaintiff's injury must flow from the defendants' competition-reducing conduct. "Courts often find a lack of antitrust injury when it views a regulatory barrier, rather than the defendant's alleged anticompetitive activities, as the cause of the plaintiff's" injuries. *Biocad JSC v. F. Hoffmann-La Roche*, 942 F.3d 88, 104 (2d Cir. 2019) (Katzmann, C.J., concurring); *cf. Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492,

507 (1988) (noting injury flowed from defendant's conduct, not any regulatory barrier). There's another problem with *Canadian Import*: "the allegedly anticompetitive behavior discouraged ***only*** unlawful importation of drugs and not lawful activity that the Sherman Act was designed to protect." 470 F.3d at 788 (emphasis added). Plaintiff's business activities are indisputably lawful.

This leaves defendants with *Pearl Music Co. v. Recording Industry Association of America, Inc.*, 460 F. Supp. 1060 (C.D. Cal. 1978), and *Maltz v. Sax*, 134 F.2d 2 (7th Cir. 1943). *Pearl* does not hold that antitrust standing is removed by plaintiff's "facilitation" of illegal conduct by others. In *Pearl*, the plaintiffs' pirated tape enterprise was "totally" criminal, because it was "a crime to manufacture and sell pirated tapes." 460 F. Supp. 2d at 1067–68 (only a "miniscule" portion of its business may have been legal). The plaintiff had no legal right to generate the revenues at issue—the law, rather than defendants' actions, prevented it.

In *Maltz*—from 1943, non-binding, and at least partially overruled—the plaintiff lacked standing because its entire enterprise "was the making and selling of goods which could only be used by purchasers in furtherance of the business of gambling." 134 F.2d at 5. Their "use" was itself prohibited by the FTC Act. *Id.* The court reasoned that the plaintiff had no protectible legal right in the business for public policy reasons unrelated to antitrust. Even if *Maltz* remains good law, it is inapposite because the record does not reflect that plaintiff's enterprise could only be used to further illegal activity; plaintiff ***does*** have a protectable legal right in its business because no federal law prohibits any of its activities and use of its service

is lawful. In any event, *Maltz* does not support a purpose-driven or geared-toward-facilitating test to deprive a plaintiff of an otherwise meritorious antitrust claim.

In fact, plaintiff is aware of no decision where standing was removed based on the percentage-share of its business that either "facilitates," or was "geared toward facilitating" illegality. *See Memorex*, 555 F.2d at 1382 (Plaintiff "had 'rights' which could be injured [and] '[t]his is all that is required. . . . Memorex's own illegal conduct did not divest it of an antitrust action.' ") (citation omitted). Such an analysis is inherently fact-intensive, not susceptible to resolution on summary judgment, and overly complex for a jury to administer. *Cf. Ill. Brick Co. v. Illinois*, 431 U.S. 720, 732, 745 (1977) (declining rule that would "greatly complicate and reduce the effectiveness of already protracted treble-damages proceedings" inconsistent with "longstanding policy of encouraging vigorous private enforcement of the antitrust laws").

Instead, under *Ayerst*, federal law itself must exclude plaintiff from the relevant markets. But no law prevents plaintiff from providing its services—indeed, such a law would violate the First Amendment, and two defendants compete in the same market. ¶ 97. Plaintiff was excluded by the conspiracy, not by operation of law.

II. DEFENDANTS DO NOT MEET THEIR INITIAL BURDEN EVEN UNDER THE GEARED-TOWARD-FACILITATING STANDARD

Defendants neither claim that plaintiff is itself engaged in illegal conduct nor that any law or regulatory scheme rather than defendants' conduct is the source of plaintiff's injury. Instead, they assert there is no genuine dispute that plaintiff's business is almost completely geared toward facilitating unlawful importation.

Mem. at 4. The set of facts they offer does not meet this flawed standard.

Defendants have the initial burden to show facts that they are entitled to judgment as a matter of law. *Powell v. Nat'l Bd. of Med. Exam'rs*, 364 F.3d 79, 84 (2d Cir. 2004). Only if defendants meet that burden must plaintiff offer "specific facts showing that there is a genuine issue for trial." *Id.* (citation omitted). Summary judgment cannot be granted where there is ***any*** admissible "evidence on which the jury could . . . find for the plaintiff." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986). The Court must view the evidence in the light most favorable to the plaintiff—even where that evidence is undisputed. *Powell*, 364 F.3d at 84; *see also Brod*, 653 F.3d at 164 (role of court is not to decide factual disputes "but to assess whether there are factual [disputes] to be tried").

In their pre-motion letter, defendants asserted that "almost all" of plaintiff's revenue is generated by international online pharmacies selling drugs to U.S. consumers. They supported this claim with calculations by their expert, Peter Kent, that (i) [redacted] of plaintiff's revenue was from foreign accredited pharmacies, (ii) U.S. visitors generated around [redacted] of click fees and made [redacted] of all clicks, (iii) [redacted] of click fees earned from U.S. visitors were paid by foreign accredited pharmacies, and (iv) almost [redacted] of all U.S. visitor clicks were to non-U.S. websites during the time period defendants chose. Dkt. 234 at 2. But on the eve of filing their motion, defendants served an amended report from Mr. Kent that revised these calculations downward because of data "anomalies." Dkt. 264 at 5. Instead, (ii) U.S. visitors generated only [redacted] of click-through fees and made only [redacted] of paid clicks, (iii)

about [redacted] of click fees earned from U.S. visitors were paid by foreign accredited pharmacies, and (iv) those U.S. visitors' clicks were to non-U.S. websites only [redacted] of the time. *See* PX 23 (redline of Kent Report).

Mr. Kent's revisions preclude summary judgment because only [redacted] of the clicks from plaintiff's website that defendants rely upon for their facilitation argument are clicks from U.S. visitors. Those clicks represent only [redacted] of click-through revenue. DSOF ¶ 40. [redacted] of clicks are non-U.S. visitors and do not even potentially implicate U.S. importation law. Defendants do not account for the clicks go to U.S. online pharmacies [redacted] and the [redacted] of plaintiff's revenue that does not come from click-through fees, DSOF ¶¶ 8, 34, but it is easy to calculate that this leaves only [redacted] of plaintiff's total revenue. *See* PSOF ¶ 32.

Defendants downplay the significance of the headline calculations they touted as material throughout discovery and through the pre-motion conference. They instead play games with statistics and reframe which metrics are relevant. *See, e.g.*, Dkt. 264 at 2 [redacted] of plaintiff's revenue is from U.S. online pharmacies, and U.S. consumers "almost exclusively" access foreign online pharmacies); DSOF ¶ 24 ("Very few U.S. pharmacies have participated in [plaintiff's] listing program."). Defendants sensationalize immaterial facts, such as that plaintiff "peddles pharmacy and drug price listings on its website to the highest bidders." Dkt. 264 at 3. And they try to bridge the gaping hole in their numbers by drawing sweeping conclusions that plaintiff focuses on or targets U.S. consumers or a forte in international prices, often mischaracterizing evidence and testimony to do so (*see, e.g.*, DSOF ¶¶ 38–39, 44–48);

they even suggest that listing prices in U.S. dollars and translating the website into Spanish implicates facilitation (DSOF ¶¶ 42–43). None of this overcomes defendants' own expert conclusion that a substantial amount of plaintiff's paid clicks could not relate to unlawful importation. This one concession demonstrates that plaintiff's business is not "completely or almost completely geared toward facilitating illegality." Mem. at 4.

III. EVEN IF DEFENDANTS COULD OVERCOME THEIR OWN SET OF FACTS, FACTUAL DISPUTES PRECLUDE SUMMARY JUDGMENT

Defendants argue that plaintiff's revenue mostly comes from click-throughs of visitors who are mostly in the United States to online pharmacies that are mostly outside the United States and, therefore, plaintiff's business is "almost completely geared toward facilitating unlawful importation." *Id.* But they skip two steps—connecting a click to a transaction and a transaction to an unlawful importation—relying on impermissible inferences instead. Equally problematic with defendants' approach is that it ignores plaintiff's specific efforts to provide information about U.S. drug prices and savings opportunities; efforts which defendants themselves thwarted.

A. Defendants Assume Substantially All Paid Clicks Lead to Drug Transactions

Defendants rely on plaintiff's click-through revenue, so they must connect that revenue to unlawful drug importation. Only [redacted] of plaintiff's click-through revenue ([redacted] of total revenue) is from U.S. visitors clicking to foreign online pharmacy websites. ¶¶ 22, 32, 40. But defendants offer ***zero*** evidentiary connection tying a single paid click by a U.S. visitor to an unlawful U.S. importation. Defendants

instead depend on an assumption that those clicks led to transactions.

Defendants try to bridge the gulf by offering only a couple examples of plaintiff responding to visitors' complaints about drug orders. But there is no evidence the drug orders referenced in those complaints resulted from a paid click. Indeed, one online pharmacy testified that not even they could determine whether a complainant had clicked through from PharmacyChecker.com. ¶ 57. They might have complained to PharmacyChecker.com for the same reason a consumer might complain to the Better Business Bureau or Consumer Reports: so there's more at stake than satisfying one customer.

One online pharmacy testified that only [redacted] of paid clicks from PharmacyChecker.com resulted in a drug transaction. ¶ 22. If this were representative of all pharmacies' paid clicks—it might be fewer—it would still mean that only a fraction of a fraction of plaintiff's revenue is connected to a click that potentially results in a drug transaction. Defendants' approach also assumes a U.S. importation resulted, even though resulting orders could have shipped to other countries—by a parent for a child studying abroad, or a foreign national ordering medicine for a family member in her home country. Despite all these necessary assumptions, defendants still come up short because another impermissible inference must be drawn in their favor: all those importations were unlawful.

B. Defendants Assume Substantially All Clicks Lead to Unlawful Importation

Defendants' theory requires yet another impermissible inference in their favor: that all resulting U.S. importations were unlawful. But the importation of

drugs into the United States is not always unlawful and the evidence suggests a different conclusion: if an importation to the United States were to follow a click from PharmacyChecker.com, that importation is more likely to be lawful because of plaintiff's verification program requirements.

1. Importation to the United States is not always unlawful

Defendants claim that "personal importation of prescription drugs is unlawful" and that plaintiff's FDA expert, Ben England, "testified that he is unaware of any law that permits personal importation from PCC-accredited online pharmacies." Mem. at 1–2. Both claims are wrong. *See, e.g.*, 21 U.S.C. §§ 352, 355, 384(j); 21 CFR 201.100, 201.122, and 201.150; Expert Rep. of Benjamin L. England, Esq., PX 4 at 12–14. Worse, defendants grossly misrepresent England's testimony.

It is unlawful to introduce ***unapproved*** drugs into interstate commerce (by import or otherwise). 21 U.S.C. § 301. But there is no prohibition on introducing FDA-approved drugs, provided other requirements are met. Approved and properly labeled drugs are *ipso facto* legal to import. "FDA has been careful to acknowledge this fact in every instance where [Personal Importation Policy] PIP is discussed . . . ." PX 4. at 13; PX 5 ("***In most circumstances***, it is illegal for individuals to import drugs or devices into the U.S. for personal use ***because these products*** purchased from other countries ***often have not been approved*** by the FDA for use and sale in the U.S."). Indeed, Congress has specifically declared that U.S. "patients" can lawfully import FDA-approved drugs—in fact, they have "reason to import into the United States drugs that have been approved by the [FDA]." 21 U.S.C. § 381(g); Prescription Drug Import Fairness Act of 2000; Pub. L. 106-387, § 1(a), 114 Stat.

1549 (Oct. 28, 2000) (enacted into law § 746(b) of Title VII of H.R. 5426 (114 Stat. 1549A-40), as introduced on Oct. 6, 2000).

It is also legal to import approved drugs that are not properly labeled but that qualify for a labeling exemption. Most pertinent in this context is the labeling exemption under 21 CFR 201.100. "[T]he fact that labeling does not conform to the FDCA requirements for adequate directions for use does not make the drug misbranded if it is dispensed by the pharmacy pursuant to a valid prescription, [which among other factors described in the regulation] bring the drug within a drug labeling exemption." PX 4 at 13.

Furthermore, Congress directed the Secretary of Health and Human Services to use discretion to permit individuals to import prescription drugs for their own use that do not represent an unreasonable risk. 21 U.S.C. § 384(j)(1). Congress also directed that "[t]he Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis . . . so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted." 21 U.S.C. § 384(j)(2)(B). PIP is that guidance. As the FDA states on its website, "The FDA has guidance for personal importation of drug or device products." ¶ 2; PX 5. For prescription drugs, personal importation is permitted under the policy if certain factors apply including, for example, the product does not represent an unreasonable risk, the product is for personal use, and the quantity is not more than a three-month supply. *Id.* The FDA has pointed to Section 384(j) "[a]s

evidence that the Congress is aware of and agrees" it can "allow the 'importation of drugs that are clearly for personal use.' " *Cook v. Food & Drug Admin.*, 733 F.3d 1, 10 (D.C. Cir. 2013) (citing § 384(j)(1)(B)).

Defendants again rely almost entirely on *Canadian Import*, 470 F.3d 785, now to argue personal importation is always unlawful. The case considered only a class of U.S. plaintiffs who, as alleged, purchased certain drugs in the United States also sold in Canada with different labeling; the manufacturer defendants had cut supplies to Canadian pharmacies of those specific drugs. But "the Canadian prescription drugs at issue are not labeled in conformity with federal law," and were therefore illegal to import under the provisions the class invoked. *Id.* at 789–91.

Canadian Import stated the specific drugs, as alleged, could not be lawfully imported because they are (1) not approved in accordance with 21 U.S.C. § 355, (2) not labeled as required by 21 U.S.C. § 352, or (3) not dispensed pursuant to a valid prescription as required by 21 U.S.C. § 353(b)(1). *Id.* at 788–89.

But many drugs sold in Canada ***are*** FDA-approved drugs under 21 U.S.C. § 355. Indeed, the HHS recently promulgated a final rule premised on this fact: it allows wholesale importation of prescription drugs "that could be sold legally on either the Canadian market or the American market with the appropriate labeling." 85 Fed. Reg. 62094. And while drugs that are not labeled as required by 21 U.S.C. § 352 can be misbranded, they are not misbranded if they qualify for a

labeling exemption. *See, e.g.*, 21 CFR 201.100.[4] *Canadian Import*'s reference to the prescription requirement is worth noting because plaintiff's accreditation program requires that pharmacies only dispense drugs pursuant to a valid prescription.

Canadian Import also makes clear and unforced errors relating to the way the regulatory scheme works. For example, it stated that "More fundamentally, that the Canadian drugs are mislabeled under federal law illustrates why the Canadian drugs are 'unapproved' drugs within the meaning of 21 U.S.C. § 355 . . . ." *Canadian Imp.*, 470 F.3d at 789. But approved drugs do not become unapproved drugs by being "mislabeled." They may be "misbranded" approved drugs, but only if no labeling exemption applies. PX 6 at 166:16–167:3 (dep. of Benjamin L. England, Mar. 16, 2022) (approved drugs from an FDA-approved facility that "by the time that it gets to the U.S., it enjoys the prescription drug labeling exemption because of the – the dispensing" are still FDA-approved drugs, not unapproved drugs or foreign versions of FDA-approved drugs).

Likewise, the opinion depends on characterizing the regulatory scheme as a "closed system." But there simply is no closed system when it comes to drugs manufactured outside the United States, which is the vast majority of them. *Id.* at 226:20–227:4 ("FDA doesn't have a closed system. There is no such thing as an FDA

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4. *Canadian Import* mistakenly said that the drugs at issue did not bear the "Rx only" symbol and therefore violated 21 U.S.C. § 353(b)(1) as necessarily misbranded. This is wrong because drugs in the United States do not have to include the symbol "Rx Only," they need only indicate that a prescription is required: A drug is misbranded if at "any time prior to dispensing the label of the drug fails to bear, ***at a minimum***, the symbol 'Rx Only.' " 470 F.3d at 789 (emphasis added).

closed system."); 231:3–11 ("The FDA doesn't have a closed distribution system, certainly not in a foreign environment."); 260:11–20 (closed system a misnomer for drugs made outside United States even if a finished drug subject to the NDA); 261:1–10 ("It's just not a closed system, whether it's for personal importation or commercial distribution.").

Canadian Import reasons that "By creating [a] comprehensive regulatory system, . . . Congress has effectively precluded importation of these drugs, absent the sort of special authorization contemplated by 21 U.S.C. § 384." 470 F.3d at 790–91. Section 381 is the statute that restricts drug importation. And yet drugs come in from all over the world—and not just for personal importation—under Section 381 and without a "special authorization" under another statute. PX 6 at 263:19–264:10. Section 381 prohibits importing "adulterated, misbranded, or [an unapproved new drug] in violation of section 355"; it also prohibits the ***reimportation*** of approved prescription drugs. 21 U.S.C. § 381(a), (d). But despite specifically prohibiting reimportation of approved drugs, the statute titled "Imports and exports" contains no express prohibition on approved drugs that are not misbranded, adulterated, or reimported. *See generally* 21 U.S.C. § 381; *see also Cook*, 733 F.3d at 7 ("§ 381(a) sets forth precisely when the agency must determine whether a drug offered for import appears to violate the FDCA.").

Defendants further claim, citing *Canadian Import*, that § 384(j) is not yet in effect, citing § 384(l)(1), which states, "Commencement of Program. This section shall become effective only if the Secretary certifies to the Congress that the

implementation of this section will (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer." But the next provision specifies that the section or "program" to which it is referring is the wholesale importation program under subsection (b), not (j). 21 U.S.C. § 384(l)(2) ("Termination of Program. (A) . . . If, after the date that is 1 year after the effective date of the regulations under subsection (b) and before the date that is 18 months after the effective date, the Secretary submits to Congress a certification that . . . the benefits of implementation of this section do not outweigh any detriment . . . this section shall cease to be effective . . . ."). Section 384(j) has a separate declaration that "the Secretary should . . . (B) exercise discretion to permit" personal importation (§ 384(j)(1)), grants the Secretary "waiver authority" (§ 384(j)(2)), and mandates publication of guidance "that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis . . . so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted." 21 U.S.C. § 384(j)(2)(B). "It is a fundamental canon of ***statutory construction*** that the words of a statute must be read in their context and with a view to their place in the overall ***statutory*** scheme." *West Virginia v. EPA*, Nos. 20-1530, 20-1531, 20-1778, 20-1780, 2022 WL 2347278, at *34 (2022) (emphasis added).

2. Plaintiff's verification program filters out unlawful importations with requirements consistent with lawful importation

Defendants lean on the FDA's occasional statement that "virtually all" personal drug importation is illegal. "Virtually all" necessarily implies *not* "all"

personal drug importation is unlawful. Regardless, it does not follow that "virtually all" or "substantially all" or even "most" of the unknown proportion of paid clicks by U.S. visitors from PharmacyChecker.com to foreign online pharmacies lead to unlawful importations because plaintiff's verification program requirements narrow the circumstances under which a personal importation to the United States might occur. Plaintiff's verified online pharmacies must meet standards that mirror common requirements for lawful importation. All online pharmacies in the verification program must:

- Be a licensed pharmacy in good standing that at all times employs a licensed pharmacist (2.1, 2.14–2.19)
- Not market, sell, process, and/or dispense prescription orders for controlled substances to patients in the United States (or must possess valid DEA registration) (2.12–13, 7.0–7.6)
- Require a prescription by a licensed healthcare provider (3.0–3.10)
- Not market, sell, or intentionally reimport medications manufactured in the United States that were then exported (5.0)
- Dispense only a maximum three months' supply of medications for personal use (10.0-10.1)
- Comply with all applicable medication labeling and storage requirements, including any FDA-required black box warnings (11.0-11.11)

See ¶ 60; PX 27.

Plaintiff monitors its verified pharmacies' compliance with its practice and

safety standards through periodic audits, employing mystery shopping, remote monitoring of websites, and on-site inspections. ¶ 60; PX 27, 28.

Since prescription drug importation is lawful for FDA-approved drugs that are properly labeled or qualify for a labeling exemption (e.g., 21 CFR 201.100 (requiring prescription, etc.)) and unapproved drugs can be imported under the PIP when meeting certain requirements to establish they are for personal use (e.g., maximum 90-day supply), clicks by U.S. visitors from PharmacyChecker.com to non-U.S. verified pharmacies that lead to drug transactions and importation to the United States are far more likely to be legal because of these requirements. Indeed, Mr. England concluded that plaintiff's verification program as written is consistent with lawful importation because it includes these requirements. PX 4 at 5.

C. Plaintiff's Efforts to Verify and List U.S. Pharmacies Have Been Thwarted by Defendants

Even if it were appropriate to slice and dice plaintiff's revenue to determine if plaintiff's enterprise is "almost completely geared toward facilitating illegality," defendants' statistics do not account for their anticompetitive conduct's effect on plaintiff's enterprise. Mem. at 4.

About [redacted] of plaintiff's accreditation revenue during the time period studied by defendants came from U.S. online pharmacies, as did nearly [redacted] of its click-through revenue. ¶¶ 22, 34. A total of [redacted] U.S. pharmacies have participated in plaintiff's programs since January 2015, and the number is now only [redacted] ¶¶ 24, 28. PharmacyChecker.com actively features its U.S. prescription discount card, but with limited success from a bottom-line revenue standpoint (largely for U.S. generics,

which tend to be lower priced than they are outside the United States). ¶¶ 11–12. Indeed, plaintiff has been working for years—since interest in its program among U.S. pharmacies began waning—to provide more useful information on how U.S. visitors can save money from prescription drugs in the United States. ¶ 11.

Defendants thwarted those efforts. U.S. pharmacies have been coerced or dissuaded from participating in plaintiff's verification and listing programs because of defendants' conduct. ¶¶ 9, 24–25. Indeed, long after the alleged conspiracy began, defendant NABP threatened to strip [redacted] VIPPS accreditation on two separate occasions in 2017 and 2018 if it participated in plaintiff's programs or otherwise publicly associate with plaintiff. ¶ 24. Defendants targeted U.S. advertisements to dissuade both online pharmacies and consumers from associating with or utilizing plaintiff's services. *Id.* Blacklisting plaintiff and working with search engines to wipe it from visible search results has likely also had an outsized effect in the United States.

Plaintiff does not know the full extent of defendants' conduct that has thwarted its ability to recruit U.S. online pharmacies to participate in its verification and listing programs or in its ability to market the U.S. online and discount options that it does offer. *Id.* It has not been permitted to take that discovery. But there is evidence that plaintiff consistently tried to obtain more U.S. online pharmacy participation and to provide more information generally to U.S. visitors about domestic drug price savings. ¶¶ 11, 24. On that basis alone, a jury could conclude that if plaintiff's business is "almost completely geared toward facilitating illegality"

it is because of defendants' anticompetitive acts. Mem. at 4. That is undoubtedly the type of injury the antitrust laws were designed to prevent.

CONCLUSION

For the foregoing reasons, PharmacyChecker.com respectfully requests that the Court deny defendants' joint motion for summary judgment.

Respectfully submitted,

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By: *S/Aaron Gott*

AARON GOTT (admitted *pro hac vice*)

aaron.gott@bonalawpc.com
BONA LAW PC
331 2nd Avenue South #420
Minneapolis, MN 55401
(612) 824-5001

James Lerner (2371599)
james.lerner@bonalawpc.com
287 Park Avenue South, Suite 422
New York, NY 10010
(212) 634-6861

Counsel for Plaintiff
PharmacyChecker.com

CERTIFICATE OF SERVICE

I, Lisa Mittwol, hereby certify that on this 20th day of July 2022, I caused a copy of Plaintiff's Opposition to Defendants' Joint Motion for Summary Judgment on Sherman Act § 1 Claim be served upon counsel of record via the Court's electronic filing system.

Lisa Mittwol

LISA MITTWOL